

## **REMARKS**

Claims 1- 9, 11-16, and 113-133 constitute the pending claims in the present application. Claims 134-140 are new. Claims 1 and 125 have been amended. These amendments serve to expedite prosecution of the application and to further define a preferred embodiment of the claimed invention but are not meant to limit the scope of the present invention. Applicants reserve the right to pursue claims of similar or differing scopes in future applications.

No new subject matter has been added, and the amended and new claims should not necessitate an additional search. Support for the amended and new claims can be found in the application as originally filed. For example, support for the amendments to the claims regarding one or more passive detection elements wherein no voltage difference external to the medium is applied to said one or more passive detection elements can be found in the application in the examples (see e.g., pages 28-30) and figures (see e.g., Figures 1.4 and 2.1). New claims 134-136 correspond to original claims 63-65. Support for new claims 137-140 regarding the use of a magnetized electrode can be found in the application in the specification (e.g., page 9, lines 30-33 to page 10, line 1 and page 14, lines 20-22) and in the examples (see e.g., pages 28-30).

The issues raised by the Examiner in the outstanding Office Action are addressed below in the order they appear in the prior Action.

### **Telephone Interview**

Applicants' agent, Kathleen Ehrhard, wishes to thank Examiner Nelson Yang for granting a telephonic interview on July 19, 2005 to discuss the Office Action. During the interview, Applicants' agent requested clarification regarding the Examiner's reference to "examples" on page 11 of the Action. Applicants' agent requested clarification whether the use of the term "examples" referred to in the second paragraph of page 11 was the same as "examples" referred to in the paragraph immediately following on page 11 of the

Action, where the Examiner states that the “examples” provide more detailed steps as to how the method is performed that are novel over the cited art.

The Examiner confirmed that the use of the term was different in each paragraph and that “examples” in the second paragraph on page 11 of the Action refers to the specific examples of stimuli provided on page 11, lines 24-26 of the specification whereas “examples” in the third paragraph beginning on page 11 of the Action refers to the working examples provided in the specification beginning on page 28.

The Examiner acknowledged in the interview that the working examples provide examples of electrodes to which no electrical stimulus has been externally applied. Applicants’ agent referred to figures in the specification that detail the electrodes as inert and not interacting with the medium.

In light of the discussions with the Examiner, Applicants have amended claims 1 and 125 to recite that “no voltage difference external to the medium is applied to said one or more passive detection elements”.

The Claims Comply with 35 U.S.C. §112

Rejection of Claims 130-133 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph

Claims 130-133 are rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

In particular, the Examiner has rejected Claims 130-133 as vague and indefinite because “it is unclear how the transient electrical signal giving rise to a decaying waveform is generated and controlled, such that the waveform decays in 1 minute to 1 millisecond, or 5 seconds to 10 milliseconds”. The Examiner contends that “it is unclear if applicant is limiting the analytes to be detected to those that would produce such a transient electrical signal” or if “this limitation is the result of some undisclosed structural element or method step, or...is a property inherent to the method itself”.

Applicants have amended claims 1 and 125, from which claims 130-131 and 132-133 respectively depend, to clarify that the transient electrical signal is “produced” by a

monodirectional movement of said first molecule through said conducting medium sample relative to said immobilized second molecule. Moreover, Applicants point out that the claims recite that the transient electrical signal thus produced “is measured using said first working electrode”.

Applicants believe the aforementioned amendments and discussion obviate the Examiner’s rejection of claims 130-133 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

The Claims Comply with 35 U.S.C. §102

Rejection of Claims 1-3, 5, 7, 11-13, and 15 under 35 U.S.C. 102(b) [Park et al In vivo nitric oxide sensor using non-conducting polymer-modified carbon fiber (1998) Biosensors & Bioelectronics 13:1187-1195]

Claims 1-3, 5, 7, 11-13, and 15 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Park et al. Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The standard for anticipation is that “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1 as amended recites, in part, detecting a transient electrical signal using a first working electrode, wherein the first working electrode is a passive detection element and wherein ***no voltage difference external to the medium is applied*** to said one or more passive detection elements. [Emphasis added]

Park et al. do not disclose detecting a transient electrical signal as recited in the pending claims. Detection of a signal in the Park et al. disclosure requires that a voltage difference external to a conducting medium sample be applied, such as a potential applied to the working electrode in a PBS solution (see e.g., Figure 2 and the paragraph bridging

pages 1188 to 1189). This is in contrast to the amended claims that recite detecting a transient electrical signal that is measured using a first working electrode, “wherein said first working electrode is a passive detection element” and “wherein no voltage difference external to the medium is applied to said one or more passive detection elements”. Park et al. fail to teach or suggest the detection of a transient electrical signal using passive detection elements to which a voltage difference external to the medium is *not* applied, such as the use of the first working electrode recited in the pending claims.

Claims 2-3, 5, 7, 11-13, and 15 are dependent on claim 1. As discussed above, claim 1 is not anticipated by Park et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the dependent claims of claim 1 are thus not anticipated by Park et al. Accordingly, Applicants submit that Park et al. do not anticipate the pending claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-5, 7, 9, 11-14, 113, 117, 119-121, 123-125, 127, and 129-133 under 35 U.S.C. 102(e) (Wang et al US 6,468,785)

Claims 1-5, 7, 9, 11-14, 113, 117, 119-121, 123-125, 127, and 129-133 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Wang et al (US 6,468,785). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Claims 1 and 125 as amended recite, in part, detecting a transient electrical signal using a first working electrode, wherein the first working electrode is a passive detection element and wherein ***no voltage difference external to the medium is applied*** to said one or more passive detection elements. [Emphasis added]

Wang et al. do not disclose detecting a transient electrical signal as recited in the pending claims. Wang et al. require that a voltage difference be applied that is external to a medium, such as a potential applied to the working electrode in order to detect DNA

hybridization in a solution (see e.g., column 8, lines 53-54). In contrast, the pending claims recite detecting a transient electrical signal that is measured using a first working electrode that is a passive detection element, “wherein no voltage difference external to the medium is applied to said one or more passive detection elements”. Wang et al. fail to teach or suggest detecting a transient electrical signal by using a passive detection element to which a voltage difference external to the medium is *not* applied.

In addition, claims 2-5, 7, 9, 11-14, 113, 117, 119-121, 123-125, 127, and 129-133 are dependent on either claim 1 or claim 125. As argued above, claim 1 and claim 125 are not anticipated by Wang et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claims 1 and 125 are thus not anticipated by Wang et al. Accordingly, Applicants submit that Wang et al. do not anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claims 1-3, 5, 7-9, 11-13, and 15 under 35 U.S.C. 102(b) (Yacynych US 5,540,828)

Claims 1-3, 5, 7-9, 11-13, and 15 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Yacynych (US 5,540,828). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

At most, Yacynych discloses amperometric detection of an analyte, which requires a detection element to which a voltage difference external to the sample medium has been applied, such as an electrode immersed in a solution of monomer to which an electric current has been applied (see e.g., the abstract). In contrast, claim 1 recites detecting a transient electrical signal that is measured using a first working electrode that is a passive detection element, “wherein no voltage difference external to the medium is applied to said one or more passive detection elements”. Yacynych fails to teach or suggest this element recited in the pending claims.

In addition, claims 2-3, 5, 7-9, 11-13, and 15 are dependent on claim 1. As discussed above, claim 1 is not anticipated by Yacynych. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claim 1 are thus not anticipated by Yacynych. Accordingly, Applicants submit that Yacynych does not anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claims 1-3, 6-8, 11-13, 15, 113-118, and 125-128 under 35 U.S.C. 102(b) (Saini et al US 5,521,101)

Claims 1-3, 6-8, 11-13, 15, 113-118, and 125-128 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Saini et al. (US 5,521,101). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

At most, Saini et al. disclose electrochemical detection of an analyte in a method that requires an applied voltage difference external to a gaseous medium, such as an applied potential to electrodes comprising an enzyme-mediator solution in the presence of gaseous H<sub>2</sub>O<sub>2</sub> (see e.g., column 10, Example 1). In contrast, claims 1 and 125 recite detecting a transient electrical signal that is measured using a first working electrode, “wherein said first working electrode is a passive detection element” and “no voltage difference external to the medium is applied to said one or more passive detection elements”. Saini et al. fails to teach or suggest this element recited in the pending claims.

In addition, claims 2-3, 6-8, 11-13, 15, 113-118, and 126-128 are dependent on either claims 1 or 125. As argued above, claim 1 and claim 125 are not anticipated by Saini et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claims 1 and 125 are thus not anticipated by Saini et al. Accordingly, Applicants submit that Saini et al. do not anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claims 1-3, 5-9, 13-16, 113-121, and 125-129 under 35 U.S.C. 102(e) (Fukushima et al US 6,762,050)

Claims 1-3, 5-9, 13-16, 113-121, and 125-129 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Fukushima et al (US 6,762,050). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Fukushima et al. do not disclose detecting a transient electrical signal as recited in the pending claims. Fukushima et al. disclose a sensor device for the detection of an analyte, such as a biological substance, in a method that requires that a voltage difference external to a sample (such as liquid or gas samples, see column 5, first paragraph, and column 6, fourth paragraph) be applied to the sensor device, such as application of a constant current or constant voltage (see e.g., column 5, lines 39-43 and 54-60). In contrast, the pending claims recite detecting a transient electrical signal using a working electrode to which a voltage difference external to the medium is *not* applied. Fukushima et al. fail to teach or suggest this element recited in the pending claims.

In addition, claims 2-3, 5-9, 13-16, 113-121, and 126-129 are dependent on either claims 1 or 125. As argued above, claim 1 and claim 125 are not anticipated by Fukushima et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claims 1 and 125 are thus not anticipated by Fukushima et al. Accordingly, Applicants submit that Fukushima et al. do not anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

For the reasons stated above, Applicants submit that the claimed invention is not anticipated by the cited references. Applicants submit that none of the cited references teach or suggest the detection of a transient electrical signal by a passive detection element to which a voltage difference external to the medium is not applied.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the §102 rejections.

The Claims Comply with 35 U.S.C. §103

Rejection of Claim 122 under 35 U.S.C. 103(a) [Wang et al (US 6,468,785) in view of Henkens et al (US 6,391,558)]

Claim 122 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Wang et al. (US 6,468,785) in view of Henkens et al. (US 6,391,558). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The Examiner's attention is drawn to MPEP § 706.02(j), which sets forth that a teaching or suggestion provided by the prior art reference (or references when combined) of all the claimed limitations is necessary to establish a *prima facie* case of obviousness. The following comments address this requirement of a rejection under 35 U.S.C. § 103(a).

Wang et al. is discussed above. Henkens et al. disclose an electrochemical detection system in which a biochemical reaction generates a measurable current when a voltage difference external to a sample, such as a liquid biological sample, is applied, namely, when an amperometric potential is applied. Neither Wang et al. nor Henkens et al., either alone or in combination, teach or suggest detecting a transient electrical signal that is measured using a first working electrode that is a passive detection element “wherein no voltage difference external to the medium is applied to said one or more passive detection elements”, as is recited in the pending claims.

For the foregoing reasons, Applicants believe that the references cited by the Examiner do not render the claimed subject matter *prima facie* obvious under 35 U.S.C § 103(a). Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claim 122 under 35 U.S.C. 103(a) [Fukushima et al (US 6,762,050)  
in view of Henkens et al (US 6,391,558)]

Claim 122 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Fukushima et al. (US 6,762,050) in view of Henkens et al. (US 6,391,558). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Fukushima et al. and Henkens et al. are discussed above. Neither Fukushima et al. nor Henkens et al., either alone or in combination, teach or suggest detecting a transient electrical signal that is measured using a first working electrode that is a passive detection element to which no voltage difference external to the medium is applied, as is recited in the pending claims.

For the foregoing reasons, Applicants believe that the references cited by the Examiner do not render the claimed subject matter *prima facie* obvious under 35 U.S.C § 103(a). Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

## CONCLUSION

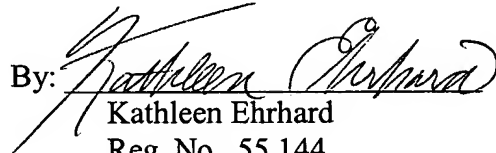
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the pending claims are in condition for allowance, and early and favorable reconsideration is respectfully solicited.

If there are any other fees due in connection with the filing of this Response, please charge the fees to our **Deposit Account No. 18-1945** under Order No. SUPP-P01-012.

Respectfully submitted,

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